

REMARKS

By this Response, claims 19 and 54 have been amended. Claims 1-18, 20, 24, 26, 28-34, 36, 38-40, 42, 44-48, and 50-52 have been previously canceled. No further claims have been canceled or added. Claims 19, 21-23, 25, 27, 35, 37, 41, 43, 49, and 53-56 remain pending. Support for the amendment to claim 19 can be found throughout the as-filed specification and claims, in particular at page 21, line 18 of the original application. No new matter has been added.

Interview Summary

At the outset, the Examiner is thanked for the consideration given during the Interview of June 18, 2008. During the Interview, all claims and prior art of record were discussed, along with proposed claim amendments thereto. The remaining substance of the Interview can be found throughout the following discussion.

Rejections Under 35 U.S.C. § 112, First Paragraph

In the Office Action, the Examiner rejected claim 25 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed.

The Examiner specifically asserts that the recitation in claim 25 of thermal insulators providing insulation between the segments is not supported by the specification.

Claim 25 recites "wherein the segments are insulated from each other with a thermal insulator inserted in a gap between adjacent segments". It is respectfully

submitted that originally filed claim 5 included this same language, reciting "the individual segments (8) are thermally decoupled by means of a gap, formed between adjacent segments (8), in which a thermal insulator is inserted". In addition, each of FIGS. 6-9 and the related disclosure describe the segments of the reaction vessel receiving element connected by means for thermally insulating webs 24. See, for example, page 11, lines 15-17 and 24-26 of the original specification.

Accordingly, it is believed that the subject matter of claim 25 fully complies with the written description requirement and the rejection with respect thereto under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

In the Office Action, the Examiner rejected claims 19, 21-23, 25, 27, 35, 37, 41, 43, 49 and 53-56 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

It is the Examiner's position that the language of claims 19, 41 and 49 are unclear as to whether or not the intended structure includes any actuating means and a controller to provide the cited functionality. Additionally, it is unclear to the Examiner what structural features would configure the reaction vessel receiving element for holding specifically a single non-conductive multi-well plate. It is also unclear to the Examiner whether or not electrical conductivity is meant. Finally, in reference to each heating/cooling device corresponding to one segment, it is unclear to the Examiner

whether or not all the devices are connected to the same segment, or whether a one-to-one relationship between the devices and the segment is meant.

With regard to claim 25, the Examiner questions how a gap filled with air can serve the goal of thermal decoupling of segments, since thermal conductivity of known solid insulating materials is higher than that of air.

With regard to claim 54, the Examiner considers the language "residence time of at least one ... temperature" to be unclear.

Responsive to the Examiner's comments, it is respectfully submitted that breadth of a claim is not to be equated with indefiniteness according to MPEP 2173.04 and *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. § 112, second paragraph. Further, the "controller" is recited in, for example, dependent claim 56 which further limits the subject matter of claim 19 by reciting a control unit for actuating the two or more devices. Accordingly, no amendments appear to be required in connection with claim 19.

Next, the physical structure of the reaction vessel receiving element need not be described further because it is a positively recited element which is fully supported by the specification. Support for the claim can be found in at least page 7, lines 14-16 of the original specification.

With regard to the Examiner questioning whether the term non-conductive includes electrical conductivity; this phrase is intended to refer to lack of thermal

conductivity as is characteristic of a standard microtiter plate, however the claim has been amended to remove this phrase.

With regard to each heating/cooling device corresponding to one segment, it is believed that this language is clear as having a one-to-one correspondence of device to segment. Support for this relationship is found throughout the specification and claims, for example FIGS. 1 and 2 and page 7, lines 4-5 reciting "(m)ounted on each of the bases 5a is a heat exchanger 6, a Peltier element 7 and a segment 8 of a reaction vessel receiving element." (Emphasis added).

Continuing, claim 25 refers to a thermal insulator (for example element 24 of FIGS. 6-9) rather than an air gap. In any event, air is a sufficient insulator for the claimed invention and is recited in dependent claim 23.

Finally, claim 54 has been amended to recite "residence time at a temperature for at least one of denaturing temperature, annealing temperature, and elongation temperature".

Accordingly, all claims are now believed to be fully definite within the meaning of 35 U.S.C. § 112, second paragraph, and the rejection with respect thereto should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

In the Office Action, the Examiner rejected claims 19, 21-23, 25, 27, 35, 37 41, 43, 49 and 53-56 under 35 U.S.C. § 103(a) as being unpatentable over *Gordon et al.* (U.S. Patent No. 5,601,141) in view of *Potter et al.* (U.S. Patent No. 5,819,842). This rejection is respectfully traversed.

Claim 19 is directed to a system for optimizing parameters for PCR, the system comprising: a reaction vessel receiving element, wherein the reaction vessel receiving element is configured to receive one multi-well standard microtiter plate and wherein the reaction vessel receiving element is divided into two or more segments that are thermally insulated from one another; and two or more devices for heating and cooling the reaction vessel receiving element, wherein each device corresponds to only one segment; wherein the devices are actuated independently of one another to set and maintain different temperatures in two adjacent segments; wherein the system provides different temperatures to the segments during a temperature cycle to optimize the parameters for PCR.

It is the Examiner's position that *Gordon et al.* disclose a modular thermocycler having a base and an array of modules (segments) mounted on the base, and that the modules are formed in three layers – a sample plate, a heater plate, and a cooling plate. The Examiner recognizes that each module supports a single microtiter plate and that a single standard microtiter plate does not span multiple modules. Thus, *Potter et al.* are applied as disclosing a sample plate 10 having wells 13, where the temperature in each well is independently controlled by heat controlling segments 21 of sample vessel receiving structure 20.

As discussed with the Examiner in the Interview of June 18, 2008, *Gordon et al.* are deficient in at least two respects, including providing exactly one microtiter plate per module, and having a cooling device spanning a row of modules. In distinction, the present invention claims a segmented reaction vessel receiving element configured to receive one standard microtiter plate (noting that the standard microtiter plate thereby

spans all segments of the reaction vessel receiving element). Further, each (heating/cooling) device corresponds to one segment in the claimed system rather than having a cooling portion span a row of modules as in *Gordon et al.*

The Examiner commented in the Office Action that the modules of *Gordon et al.* are "capable" of supporting a single plate. To the contrary, while *Gordon et al.* may be "capable" of supporting some type of non-standard plate, a standard microtiter plate is only and specifically disclosed as being supported by a single module. Thus, the device of *Gordon et al.* is of a size that a standard microtiter plate can only align with a single module, and not multiple modules. The clear intent of *Gordon et al.* is to provide a single plate per module. *Gordon et al.* describe the problems associated with operating "on only one plate" and solve this problem by using multiple plates and corresponding modules (see at least column 1, lines 38-44, column 2, lines 2-3, and column 6, lines 57-59 thereof). To provide a single standard microtiter plate over the plural modules of *Gordon et al.* therefore appears to be an impossibility according to the teaching and function of *Gordon et al.*

Potter et al. are applied as disclosing a device for "independent control of multiple samples which are in close proximity" and as disclosing Peltier thermoelectric devices as possible heat controlling elements. Even assuming, *arguendo*, that *Potter et al.* disclose these features, it is respectfully submitted that the "cooling" in *Potter et al.* is with a cold block 25 which spans an entirety of the sample plate 10 rather than corresponding to one segment as claimed. For this reason, the cooling device of *Potter et al.* is the same as *Gordon et al.* and fails to modify *Gordon et al.* in a manner which would render the claimed invention obvious. Finally, *Potter et al.* fail to disclose a

standard microtiter plate as claimed. Thus, even in combination, *Gordon et al.* and *Potter et al.* fail to teach or suggest the claimed invention.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 19, 21-23, 25, 27, 35, 37 41, 43, 49 and 53-56 under 35 U.S.C. § 103(a). Applicants respectfully submit that claims 21-23, 25, 27, 35, 37 41, 43, 49 and 53-56 are in condition for allowance, at least by virtue of their dependency from allowable claim 19.

Double Patenting Rejection

Claims 19 and 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of co-pending Application No. 11/470,463, claim 18 of co-pending Application No. 11/450,442, claim 18 of co-pending Application No. 11/651,986, and claim 26 of co-pending Application No. 11/651,985.

Responsive to the Examiner's indication, Applicants request that this rejection be held in abeyance until claims are patented in the identified applications.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

If the Examiner believes that additional discussions or information might advance the prosecution of the instant application, the Examiner is invited to contact the undersigned at the telephone number listed below to expedite resolution of any outstanding issues.

Please grant any extensions of time required to enter this response and charge any additional required fees to deposit account 50-2961.

Respectfully submitted,

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